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May 30, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: "Q!A® Stability Testing of New Drug Substances and Products"

Dear Sir or Madam:

This draft revised guidance published in the Federal Register, April 21, 2000, contains a definition for *Retest Period* that includes the statement "After this period, a batch destined for use in the manufacture of a drug product should be retested for compliance with specifications and then used immediately." This has been interpreted by some to preclude any further retesting and subsequent use of the drug substance. This does not reflect current industry practice. It is not unusual to continue to retest and use drug substance for as long as it meets all requirements. The use of the term "immediate" undoubtedly leads to this interpretation and also does not, necessarily, reflect industry practice. If the drug substance is unstable, immediately use is appropriate. However, if the material is stable, it must only be used prior to the next retest date which will have been based on accumulated stability data. Please clarify this definition in the revised Guidance.

As a precedent, you may want to consider USP Reference Standards. It is not uncommon for a Reference Standard to be reissued, perhaps several times, as long as it continues to meet requirements. As examples, the May-June 2000 issue of Pharmacopeial Forum contains, Antipyrene, lot # F-4 (5th reissue), Benzoic Acid, lot #F-4 (5th reissue) and Biperiden HCl, lot #F-3 (4th reissue).

Thank you for your attention.

Sincerely,

Judy P. Boehlert

Judy P. Boehlert, Ph.D.
President

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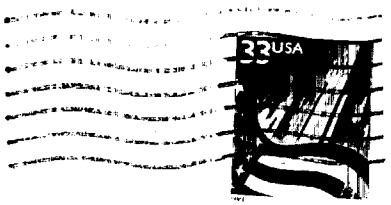

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